DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 15, 2016

TUV America, Inc.
c/o Ms. Laura Danielson
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K063657
Trade/Device Name: Vascutrak™ PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, angioplasty, peripheral, transluminal
Regulatory Class: Class II
Product Code: PNO
Dated: December 7, 2006
Received: December 8, 2006

Dear Ms. Danielson:

This letter corrects our substantially equivalent letter of December 12, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063657

Device Name: VascuTraK™ PTA Dilatation Catheter

Indications for use: The VascuTraK™ PTA Dilatation Catheter is intended for dilatation of stenoses in the peripheral arteries including the iliac, femoral, popliteal, ilio-femoral, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use: ____X____ AND/OR Over-the-counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063657

K063657
p. 1 of 2

510 (k) SUMMARY

DEC 1 2 2006

Applicant

YMed, Inc.
9925B Business Park Avenue
San Diego, California 92131
Phone: (858) 542-1760
Fax: (858) 542-1717

Manufacturer

ThermopeutiX, Inc.
9925B Business Park Avenue
San Diego, California 92131
Phone: (858) 542-1760
Fax: (858) 542-1717

Contact Person

Thomas Schroeder, Director, RA/QA

Common Name: PTA Catheter

Classification Name: Catheter, Angioplasty, Peripheral, Transluminal

Proprietary name: VascuTraK™ PTA Dilatation Catheter

Predicate Devices

The YMed VascuTraK™ Catheter is substantially equivalent in general design and use features to many currently marketed balloon dilatation catheters used for peripheral angioplasty procedures; these predicate catheters are:

1) Invatec Amphirion™ Deep PTA Catheter (K042624)
2) Cordis SAVVY® PTA Dilatation Catheter (K971010)
3) Guidant VIATRAC® 14 Peripheral Dilatation Catheter (K000101)
4) Boston Scientific Gazelle™ Balloon Dilatation Catheter (K001134)

K063657
p. 2 of 2

Indications for Use

The VascuTraK™ PTA Dilatation Catheter is intended for dilatation of stenoses in the peripheral arteries including the iliac, femoral, popliteal, ilio-femoral, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Device Description

The VascuTraK™ Catheter is a sterile single use device that consists of a flexible shaft with a single through lumen and a 24 cm distal lumen that accepts a 0.014" guidewire. The distal end of the catheter contains a semi-compliant balloon that is inflated via the central lumen. The balloon is available in various diameters and lengths.

Technological Characteristics Comparison

The catheter is equivalent in design and construction to currently marketed PTA catheters. The construction materials used have an established history of safe use in similar medical devices.

Performance and Safety

The biological safety of the device has been demonstrated through biocompatibility studies of patient contact materials in accordance with the requirements outlined in ISO 10993-1. Physical testing was performed to assure catheter integrity including verification of balloon burst pressure.

The device is supplied sterile and sterility will conform to a Sterility Assurance Level (SAL) of 10^{-6}. The supplied instructions for use provide the user with the applicable warnings and cautions during use. The device is contraindicated for the coronary arteries. There are no new safety or effectiveness issues related to this device.